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May 14, 2009

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Via Fax and Overnight Courier
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Dr. Matthias Eck
C/M/S/ Hasche Sigle
Postfach 70 02 66
D-70572 Stuttgart
Schöttlestrasse 8
D-70597 Stuttgart
Germany

Your Ref.: sec-shal-2007/17589 Our Ref.: 23134.0205

Re: Roche Diagnostics GmbH and Roche Diagnostics Corporation
Polymer Technology Systems, Inc.
Infringement Assertion

Dear Dr. Eck:

Thank you for your letter of 16 April 2009 to Mr. Robert Huffstodt regarding the potential dispute between Roche Diagnostics GmbH and Roche Diagnostics Corporation (hereinafter "Roche") and Polymer Technology Systems, Inc. (hereinafter, "PTS). PTS has asked me to respond to your letter.

PTS was amazed and disappointed in your letter as it believed it had entered into a new spirit of cooperation looking forward to mutual business with Roche. In fact, in just the last week Roche representatives in Indianapolis have contacted PTS regarding mutual business. However it seems that there is significant disconnect between the Roche Headquarters in Germany and Roche management in Indianapolis. In previous letters PTS had invited Roche to send representatives to PTS to discuss this matter privately. Since Roche Germany has ignored this invitation, we now must reluctantly inform you of information that is quite damaging to the Roche business interests.

Your letter states that you have been hired by Roche to enforce the License Agreement dated in December 2003 (the "License Agreement'). This Agreement formed part of the Settlement Agreement settling litigation in the United States District Court, Southern District Of Indiana, Indianapolis Division between the parties ("Settlement Agreement"). The License Agreement and Settlement Agreement are jointly referred to herein as the "Agreements". Since your allegations are based on general statements not supported in the Agreements, it appears that you may not have a copy of the Agreements. Copies of the License Agreement and the Settlement Agreement are enclosed. A copy of the Stipulated Final Judgment is also enclosed as Exhibit B to the Settlement Agreement. I have not enclosed Exhibit A to the Settlement Agreement as it is merely another copy of the License Agreement, and therefore would be

redundant. We respectfully request that in any further communications in this matter you refer to the precise language of the Agreements or the Stipulated Final Judgment which support your allegations.

You state that "Roche is in possession of reports and other documents which show that at least the CardioChek PA and the CardioChek produced by PTS continue to make literal use of at least one claim of U.S. Patent No. 5,366,609 ("609 Patent")". We think this matter could be cleared up rapidly if you would tell us which claim of the 609 Patent is being used, and provide us with copies of the documents which Roche alleges show such use.

The foundation on which all of your allegations rest is Roche's position that the current PTS CardioChek [redacted] You should be aware that under United States Law, arbitrators have no authority to determine patent issues unless the parties expressly agree to have the patent issues decided by the arbitrator. 28 U.S.C. 1338 and 28 U.S.C. §1295(a)(1). See also *Ballard Medical Products v. Wright*, 823 F.2d 527 (Fed. Cir. 1987). The License Agreement only states that disputes arising under the Agreement shall be decided by arbitration. It does not expressly state that patent issues will be decided by arbitration. Therefore, the issue of whether or not the 609 patent covers the CardioChek reader can only be decided by a United States District Court.

Your letter states that "PTS agreed to pay royalties based upon the Net Sales of the entire PTS system", which "system" you later state includes not only the CardioChek reader but the MEMo Chips used with the reader and all the test strips used with the reader. You say that this agreement to pay on a system including the reader, the MEMo chip and the strips is in Art. 1.9 of the License Agreement. Actually, [redacted] Clearly, the [redacted] can mean only one of the test strip, the MEMo chip, and the instrument. Clearly, it covers test strips only if the strips [redacted] Clearly, you have not even alleged that a patent claim covers a test strip. You have only [redacted] None of the claims of the 609 patent include a test strip. Therefore, based on your letter and the License Agreement, no test strips are involved here.

However, we do find your attempt to tie royalties on the test strips to the reader patent interesting. Under US law, it is illegal to tie royalties on an unpatented product to a license for a patented product, particularly, if, like Roche, the patentee has market power in the relevant market. Although, under the express language of the License Agreement, we do not think PTS agreed to such a tying, we note that even if it did, such an agreement does not excuse the tying. As stated in one case, "conditioning the grant of a patent license upon payment of royalties on products which do not use the teaching of the patent [is] misuse." *Zenith v. Hazeltine*, 395 US 100 (1968). I have instructed PTS to save your letter and use it as evidence of patent misuse and punitive damages in the United States District Court, Southern District of Indiana, Indianapolis Division if Roche continues to insist that further royalty payments are due Roche by PTS.

We also draw your attention to the fact that the PTS readers contain a memory separate from the MEMo Chip, that the information from the MEMo Chip is downloaded to the separate memory upon insertion

of the MEMo Chip, and the microprocessor in the reader is not coupled to the MEMo Chip during the analyte test. We draw your attention to the Order On Cross Motions For Summary Judgment dated 2 March 2007 in the United States District Court, Southern District of Indiana, Indianapolis Division, a copy of which is enclosed. In this decision, the Court found that a reader such as the CardioChek reader does not infringe claim 1 of the 609 Patent. This is the same Court which entered the Stipulated Final Judgment in the litigation between Roche and PTS. Under this holding also, there is no infringement of the 609 Patent by PTS.

Your client should also be aware of the fact that PTS has in its possession a Ketosite/Stat-Site system (K 911801) developed and sold in the US in 1991 by GDS Technology of Elkart, Indiana. This analyzer was described in a public submission for clearance to the FDA that was granted in July 1991. The public FDA submissions are quite lengthy and therefore a hard copy will be enclosed with the couriered copy of this letter, but a copy will not be included with the faxed letter. The Ketosite/Stat-Site system includes both a Test Card and a Test Module. The Test Module is a pluggable memory key containing the test parameters, including timing parameters. As you can see from the public FDA documents, the K911801 Test Module contains procedure routine specifications including stored values from which time values can be determined for controlling the sensor during execution of the test algorithm performed by the meter. In particular, the Stat-Site meter can perform both glucose and ß-hydroxybutyrate measurements (Letter dated April 15, 1991, page 3, Technological Features and Appendix B1, Stat-Site Meter package insert, Introduction) and the meter does all timing and calculations for the particular test procedure (Ibid, "Things To Remember for Best Results, §§3, 4, and 6) based on information contained in the Test Module (Letter of July 1, 1991 from FDA, Narrative Device Description Summary, Letter of June 10, 1001 to Teresa Wilson, §21, and Appendix A1, Keosite Test Cards, pages 5 and 6). If the 609 patent claims are broad enough to cover the CardioChek instrument, then they also cover the Ketosite/Stat-Site system. Since the priority date of the 609 patent is June 8, 1993, any claim in the 609 patent, and any of the corresponding patents in Europe, Japan, Mexico and Canada, that covers the CardioChek reader is clearly invalid. PTS has previously invited Roche to come to PTS to view the Ketosite/Stat-Site system and discuss the FDA submission, but Roche has not responded to this invitation.

The above represents only the tip of the iceberg with regard to information PTS would prefer to discuss privately with Roche rather than assert in a public dispute. We would hope that Roche Germany would respond to PTS' invitation to discuss these matters in a positive way.

Your letter also alleges that PTS neither complied with its reporting obligations since September 2006 nor was not willing to allow PricewaterhouseCoopers to audit its records as provided under the license agreement. On the contrary, I have in my possession a letter dated May 2007 from Robert S. Huffstodt, President and CEO of PTS to Mr. Brian Smiler and Dr. Hans Joaquim-Neuer, Senior Director of Roche, providing a royalty report through March 2007 and asserting that under the Licensing Agreement PTS is not obligated to provide royalty reports if there are no royalty-bearing Sales of any Licensed Product. While Roche responded this letter, Roche did not contest PTS's interpretation of the agreement that no royalty reports were due under these conditions. Further, PricewaterhouseCoopers did perform an audit of PTS records. PTS has received no notice from either PricewaterhouseCoopers or Roche that disagreed with PTS records. Thus, we assume the audit was acceptable to Roche, and the only remaining

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disagreement is whether the [redacted] As mentioned above, this is a patent issue which an arbitrator has no authority to decide.

On a more personal note, I have in my possession an email from you to Mark Nelson, one of my partners, showing that, in a private meeting, you discussed confidential PTS information regarding the dispute between Roche and PTS with Mr. Nelson at the Boston AIPLA meeting in May of 2007. It would seem to me to be unprofessional on your part to have accepted representation of Roche in view of your prior access to PTS's confidential information regarding the same matter.

PTS welcomes the opportunity to settle any difference with Roche amicably and once again invites Roche to send representatives to PTS to view the device discussed herein as well as other documents and discuss how the differences may be resolved. We would hope that amicable resolution of this matter would lead to more positive mutual business.

Very truly yours,

Carl A. Forest, Ph.D., J.D.
for PATTON BOGGS LLP

CAF:ldt
Enclosures

cc: Robert S. Huffstodt